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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/658,769 | 09/10/2003 | Thomas J. Wood | IMED-0010-US | 4079 |
| 40575 | 7590 | 06/28/2005 | EXAMINER | |
| OLDS, MAIER & RICHARDSON, PLLC PO BOX 20245 ALEXANDRIA, VA 22320-1245 | | | MITCHELL, TEENA KAY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3743 | |

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/658,769

Applicant(s)

WOOD ET AL.

Examiner

Teena Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 24-27 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 28, 30-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-13 and 32, and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide support for the first, second and third portions of the input gas flow passage being disposed at an obtuse angle nor the first portion of an input gas flow passage being oriented in a downward fashion connected to a feed tube.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

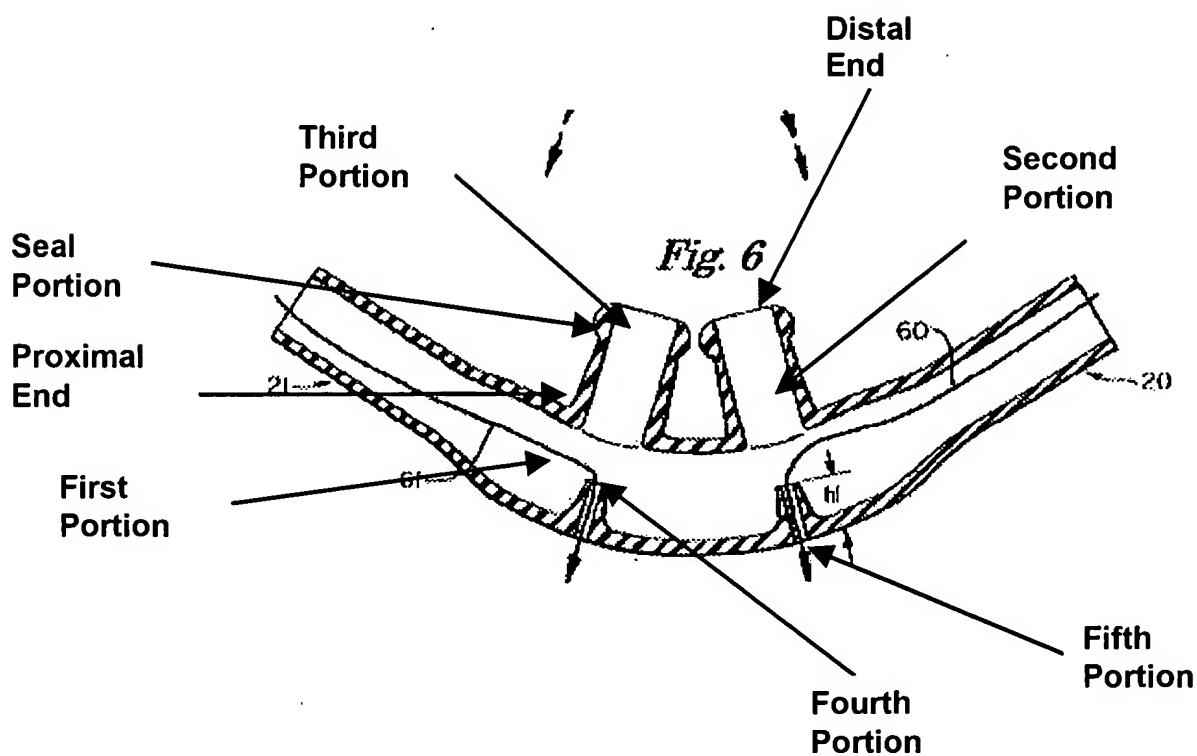
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 5, 14-18, 20-23, 28, 30, and 31 are rejected under 35

U.S.C. 102(e) as being anticipated by Strickland et.al. (6,679,265).

Strickland in a ventilation interface (10) discloses:

- a cannula (Figs. 3-7)
- with at least one nasal insert (12, 13) and at least one exhaust port (16, 17);
the cannula forming a first portion of an input gas flow passage (see illustration of Fig. 4 below) to supply the ventilation gas to the user;
- the first portion of an input gas flow passage is substantially axially aligned with the at least one nasal insert (See illustration of Fig. 6 below, the first portion is **substantially** axially aligned with at least one nasal insert)
- the at least one nasal insert forming second and third portions of the input gas flow passage from the nasal cannula to a distal end of the nasal insert; and
(see illustration of Fig. 6 below); and
- a seal portion (see illustration of Fig. 6 below) adapted to engage at least a portion of the nares, the seal portion being provided on the distal end of the at least one nasal insert;



With respect to claim 4, Strickland discloses wherein a proximal end of the nasal insert forms a second portion of the input gas flow passage having a substantially oval cross section (Figs. 2-7).

With respect to claim 5, Strickland discloses wherein a distal end of the nasal insert forms a third portion of the input gas flow passage having a substantially oval cross section (Figs. 2-7).

With respect to claim 14, Strickland discloses a gas output (16, 17) forming a portion of an output gas flow passage from the nasal insert to an exterior of the ventilation interface to channel a gas expired by the user.

With respect to claim 15, Strickland discloses wherein the second portion of the input gas flow passage formed by the nasal insert is about parallel with the portion of the output gas flow passage (Figs. 2-7).

With respect to claim 16, Strickland discloses wherein the second portion of the input gas flow passage and the portion of the output gas flow passage are configured to provide laminar flow there between (Figs. 2-7).

With respect to claim 17, Strickland discloses wherein a distal end of the gas output forms a first portion of the output gas flow passage having a substantially circular cross section (Figs. 2-7).

With respect to claim 18, Strickland discloses wherein a portion of the gas output proximal the cannula forms a second portion of the output gas flow passage having a substantially circular cross section.

With respect to claim 20, Strickland discloses wherein at least one of the nasal insert and the seal portion is sufficiently flexible to be expanded by a positive pressure provided by the ventilation gas (Col. 2, lines 41-67).

With respect to claim 21, Strickland discloses wherein at least one of the nasal insert and the seal portion forms a seal with the nares of the user by at least one of deformation of at least one of the nasal insert, the nares of the user, the seal portion or a headgear (Figs. 1-7; Col. 2, lines 41-67).

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With respect to claim 22, Strickland discloses wherein at least one of the nasal inset and the seal portion forms a seal with the nares of the user by friction (Col. 1, lines 60-67 and Col. 2, lines 41-67).

With respect to claim 23, Strickland discloses wherein at least one of the nasal inserts and the seal portion form a seal with at least one naris of the user by a resiliency of at least one of said seal portion and said nares of the user and a headgear (Figs. 1-7 and Col. 2, lines 41-67).

With respect to claim 28, note rejection of claim 1 above.

With respect to claim 30, Strickland discloses a feed tube (20) and a y-connector (22) and headgear (18).

With respect to claim 31, Strickland discloses wherein the seal portion is configured to receive a skirt to prevent leakage (Figs. 2-7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. **Ascertaining the differences between the prior art and the claims at issue.**
3. **Resolving the level of ordinary skill in the pertinent art.**
4. **Considering objective evidence present in the application indicating obviousness or nonobviousness.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 3, 6-13, 19, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strickland et.al. (6,679,265).

With respect to claim 2, Strickland does not disclose the obtuse. At the time the invention was made, it would have been an obvious matter of design consideration to have the first, second, and third portions of the input gas flow at an obtuse angle to one another because Applicant has not disclosed that having the first, second, and third portions of the input gas flow passage at an obtuse angle provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the first, second, and third portions of the input gas flow at any angle as long as there

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was laminar flow. Therefore, it would have been an obvious matter of design consideration to modify Strickland to obtain the invention as specified in claim 2.

With respect to claims 3, Strickland does not disclose the specific obtuse angle being about 135°. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the obtuse angle about 135°, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art, also because no user is alike it would be obvious based on the intended user that in order to receive the appropriate ventilation the obtuse angle would be different.

With respect to claims 6, 10, 12, 13, 19, and 32, note rejection of claim 3 above.

With respect to claim 7, Strickland discloses wherein the seal portion forms a third portion of the input gas flow passage having a substantially oval cross section (Figs. 2-7 and not illustration of Fig. 6 above).

With respect to claim 8, Strickland discloses wherein the distal end of the nasal insert includes a first exterior portion having a substantially oval cross section (Figs. 2-7).

With respect to claim 9, Strickland discloses wherein the portion of the nasal insert proximal the cannula includes a second exterior portion having a substantially oval cross section (Figs. 2-7).

With respect to claim 11, Strickland discloses wherein the seal portion includes a third exterior portion having at least one of substantially oval cross section or a round cross section (Figs. 2-7).

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With respect to claim 33, Strickland discloses wherein the feed tube has a y-connector (22).

Response to Arguments

Applicant's arguments filed 3/14/05 have been fully considered but they are not persuasive. Applicant argues that the first portion of an input gas flow passage of Strickland is not substantially axially aligned with at least one nasal insert, the examiner disagrees with this argument inasmuch the specification is not specific on what constitutes substantially axially the first portion of an input gas flow passage of Strickland does meet the claimed limitations, furthermore, applicant has not provided any criticality. With respect to the argument that Strickland does not disclose wherein the first, second, and third portions of the input gas flow passage are disposed at an obtuse angle. The examiner can find no support in the specification for the first, second and third portions at an obtuse angle but rather only the first and second portions. Also applicant fails to explain why such angle is important over any other angle, Strickland has a laminar flow through the nasal cannula regardless of an obtuse angle with respect to the first, second, and third portions. Applicant's arguments with respect to the obtuse angle are not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however on a flexible schedule.

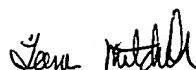
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Teena Mitchell".

Teena Mitchell
Examiner

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June 26, 2005